K101825

CONFIDENTIAL

Section 5 – 510(k) Summary or 510(k) Statement

I. General Information

SEP 2 9 2010

Submitter: C2 Therapeutics, Inc.
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Summary Preparation Date: 6/30/2010

II. Names

Device Names: CryoBalloon Ablation System

Primary Classification Names: Cryosurgical unit with a nitrous oxide cooled balloon probe and accessories

III. Predicate Devices

- CryMed Technologies SprayGenix™ Ablation System - K060555
- CSA Medical CryoSpray Ablation System - K070893
- GI Supply Polar Wand Cryotherapy System – K021387
- Barrx Medical HALO360 Coagulation System - K051168

IV. Product Description

The CryoBalloon Ablation System ("System") is used to destroy unwanted tissue by application of extreme cold. Upon activation by a physician, the balloon probe at the end of the catheter is simultaneously inflated and cooled with nitrous oxide. The balloon probe comes in contact with the wall of the esophagus and ablates unwanted tissue. Nitrous oxide is fully contained within the balloon probe and does not contact the esophagus. The nitrous oxide gas exits the patient through the proximal end of the catheter. The CryoBalloon Ablation System is designed for one time, continuous application use (single patient) in conjunction with a therapeutic endoscope (3.7mm accessory channel ID). The System is comprised of the following main components:

- CryoBalloon Ablation Catheter (REF FG-1000) consists of a connector, catheter shaft, balloon probe, and protective sheath. This is supplied sterile.

- CryoBalloon Ablation Handle (REF FG-1001) contains the cartridge heater and refrigerant delivery valve which is controlled via the trigger. The unit is internally powered (9VDC non-replaceable lithium battery pack) and supplied non-sterile.

- CryoBalloon Ablation Cartridge (REF FG-1002) contains liquid nitrous oxide. The Cartridge is supplied non-sterile and contains enough refrigerant for one to two ablation sites.

V. Indications for Use

The C2 Therapeutics CryoBalloon Ablation System is intended to be used as a cryosurgical tool for the destruction of unwanted tissue in the field of general surgery, specifically for endoscopic applications.

VI. Rationale for Substantial Equivalence

The CryoBalloon Ablation System shares the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent for use to the predicate devices as a cryosurgical unit with a nitrous oxide cooled balloon probe and accessories.

In addition, comparative performance test data demonstrated adequate device performance and safety.

Comparison Characteristic	**K10**	**K070893 & K060555**	**K021387**	**K051168**
Brand Name	**CryoBalloon Ablation System**	**CryoSpray Ablation™ & SprayGenix™ Cryo**	**Polar Wand Cryotherapy System**	**HALO 360 Coagulation System**
Intended Use				
Intended Use	Destruction of unwanted tissue with extreme cold	Destruction of unwanted tissue with extreme cold	Ablation of unwanted tissue with extreme cold	RF for tissue coagulation
Indications for Use	Intended to be used as a cryosurgical tool for destruction of unwanted tissue in the field of general surgery, specifically for endoscopic applications.	Intended to be used as a cryosurgical tool for destruction of unwanted tissue in the field of general surgery, specifically for endoscopic applications.	Used for ablation of unwanted tissue in the fields of dermatology, gynecology, general surgery, urology, and gastroenterology. The system may be used with a variety of cryogens, e.g. carbon dioxide, nitrous oxide, argon, krypton	Indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's esophagus, Dieulafoy Lesions, and Angiodysplasia.
Key Technical Characteristics				
Control	User	User	User	User
Method of Action	Thermal	Thermal	Thermal	Thermal
Endoscopic procedure	Yes	Yes	Yes	Yes

See **Table 9** – Substantial Equivalence Comparison of Intended Use and Technical Characteristics for comprehensive analysis of Technical Characteristics.

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the CryoBalloon Ablation System is substantially equivalent to the predicate devices.

Biocompatibility, performance and animal test results demonstrated the safety and effectiveness of the CryoBalloon Ablation System.

VIII. Conclusion

The CryoBalloon Ablation System was found to be substantially equivalent to the predicate devices.

The CryoBalloon Ablation System shares identical indications for use, similar design features, and functional features with, and thus is substantially equivalent to, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 2 9 2010

C2 Therapeutics, Inc.
% Mr. Peter Garcia-Meza
President and CEO
303 Convention Way, Suite 1
Redwood City, California 94063

Re: K101825
Trade/Device Name: CyroBalloon Ablation System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: June 30, 2010
Received: July 01, 2010

Dear Mr. Garcia-Meza:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K101825

Device Name: **CryoBalloon Ablation System**

Indications for Use:

The C2 Therapeutics CryoBalloon Ablation System is intended to be used as a cryosurgical tool for the destruction of unwanted tissue in the field of general surgery, specifically for endoscopic applications.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101825